

**Remarks**

By the foregoing Amendment, claim 1 is amended, and claims 12–21 are added. Entry of the Amendment, and favorable consideration thereof, is earnestly requested. Claims 1–21 are currently pending.

The present invention relates to a device for introducing a suture thread anchor into bone with a hollow guide sleeve through which a suture thread anchor can be passed. The distal end of the hollow guide sleeve has a contour which makes positioning of the distal end easier. (Par. 2). A typical use for such device includes the introduction of suture thread anchors to repair shoulder injuries and instabilities. (Par. 5). Fig. 5 shows a profile view of the glenoid margin, which is a crater-like margin of cartilage and tendinous tissue surrounding the head of the humerus in the glenoid cavity. (Par. 4). Using the claimed device, cartilage or bone part or tendon parts that have become detached from the glenoid margin are fixed in place again by introduction of a suture thread anchor whose suture thread is used to fix the tendon in place again. (Par. 9). The distal end of the claimed hollow guide sleeve, specifically the contoured end, provides a secure fit on the glenoid margin. (Par. 14).

The Applicant has amended independent claim 1 to include the limitation that the distal point is fixed relative to the front annular face of the guide sleeve. The Applicant has further amended independent claim 1 to include the limitation that said front annular face is substantially planar with the exception of said single point. The Applicant has also added new independent claim 12 and dependent claims 13–21. In addition to the limitations of claim 1, independent claim 12 requires an anchor rotator slideably disposed within said guide sleeve. (Par. 11).

Claims 1–6 Rejected Under 35 U.S.C. § 102(b) by Bonutti

The Examiner has rejected claims 1–6 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,549,630 to Bonutti (“Bonutti”). The Applicant respectfully submits that claim 1, as amended, is not anticipated by Bonutti because Bonutti does not disclose all of the elements of claim 1.

Bonutti discloses a device for introducing a suture anchor into hard tissue. (Bonutti: col. 4, ln. 60 to col. 7, ln. 32; see *also* Fig. 4–5). The device comprises a cylindrical guide sleeve (82) through which the suture anchor (10) is passed. (Id.: col. 5, lns. 9–13; Fig. 4–5). The guide sleeve (82) has a proximal end and a distal end, wherein the distal end has an annular face that is substantially perpendicular to longitudinal axis of the guide sleeve (82). (Bonutti: Fig. 4–5, *proximal end not shown for convenience*). The distal end of the guide sleeve is inserted into a circular recess in the bone tissue that receives the anchor. (Id.: col. 5, lns. 3–5; see also Fig. 4–5). An anchor (10) is passed through the guide sleeve (82) and into the bone. (Id.: col. 5; lns. 29–40).

Once the anchor (10) is inserted into the guide sleeve (82) a hollow pusher member (112) is inserted into the proximal end of the guide sleeve (82) behind the anchor (10). (Id.: col. 5, lns. 63–66). The pusher member (112) has a proximal end and a distal end, wherein the distal end has a tapered configuration. (Id. col. 6; lns. 62–66; Fig. 4–5). The pusher member (112) is used to push the trailing edge of the anchor (10) down the guide sleeve (82) and into the bone. (Id.: col. 6, lns. 62–66; Fig. 4–5). The pusher member (112) and the guide sleeve (82) are arranged in a coaxial telescoping engagement. (Id.: col. 6, lns. 27–29; Fig. 4–5). The pusher member (112) can slide freely along the longitudinal axis of the guide sleeve (82) and rotate freely about the longitudinal axis of the guide sleeve (82), but is prevented by the telescoping engagement from rotating radially about the longitudinal axis of the guide sleeve (82), i.e. the pusher member (112) and the guide sleeve (82) are coaxial. (Id.: col. 6, lns. 27–43; Fig. 4–5).

Bonutti does not anticipate the present invention as claimed in claim 1 because Bonutti is missing a single point projecting distally from said front annular face of said guide sleeve, wherein said single point is fixed relative to said front annular face. The Examiner has submitted that Bonutti discloses in figure 4 an anticipatory guide sleeve, wherein the anticipatory guide sleeve comprises the Bonutti guide sleeve (82) and Bonutti pusher member (112). (Official Action 06/28/2006 at 2; Official Action 05/17/2007 at 2). The Examiner impliedly takes the position that because the Bonutti guide sleeve (82) and the Bonutti pusher member (112) are coaxial and hollow they constitute a single 'hollow guide sleeve through which a suture anchor can be passed' as required by claim 1, although not necessarily the anchor disclosed in Bonutti. (Id.) The examiner has submitted that Bonutti discloses a single point projecting distally from the annular face of the anticipatory guide sleeve, as shown in Fig. 4, when the distal end of the Bonutti pusher member (112) is extended past the distal end of the Bonutti guide sleeve (82) during the introduction of the anchor into the tissue. (Id.). The examiner has further submitted that Bonutti discloses a shoulder between the distal end of the Bonutti pusher member (112) and the distal face of the Bonutti guide sleeve (82).

Bonutti does not anticipate claim 1, as amended, because Bonutti is missing the limitation that the single point is fixed relative to said front annular face. Bonutti discloses that the single point (on the distal end of the Bonutti pusher member (112)) and the front annular face (on the distal end of the Bonutti guide sleeve (82)) are not fixed relative to each other. Rather, Bonutti discloses that the single point (on the distal end of the Bonutti pusher member (112)) slides freely along the longitudinal axis of the Bonutti guide sleeve (82) and rotates freely about the longitudinal axis of the Bonutti guide sleeve. (Bonutti: col. 6, lns. 27–43; Fig. 4–5).

Furthermore, Bonutti does not anticipate the claimed invention as claimed in new independent claim 12 and its dependent claims because Bonutti does not disclose all of the elements of independent claim 12. As stated above, claim 12 includes the limitations of claim 1. It should be noted that Claim 12 recites a front face at the distal

end of the guide sleeve, instead of a front annular face as required by claim 1. In addition to the limitations of claim 1, independent claim 12 requires an anchor rotator slideably disposed within said guide sleeve.

Bonutti does not anticipate independent claim 12 because Bonutti is missing a single point projecting distally from said front face of said guide sleeve, wherein said single point is fixed relative to said front face, as previously discussed in this response. Bonutti is further missing an anchor rotator slideably disposed within the guide sleeve as required by new claim 12.

The Examiner has submitted that the anticipatory guide sleeve disclosed by Bonutti comprises the Bonutti guide sleeve (82) in combination with the Bonutti pusher member (112). The Examiner implied that the Bonutti guide sleeve (82) and the Bonutti pusher member (112) were anticipatory because a suture anchor could be passed through the hollow longitudinal axis of the Bonutti pusher member (112). The Applicant respectfully submits that, based on this view, Bonutti is missing an anchor rotator slideably disposed within said anticipatory guide sleeve, because Bonutti does not disclose an anchor rotator disposed within the hollow longitudinal axis of the Bonutti pusher member (112).

Furthermore, the Applicant respectfully submits that it is not obvious to combine the Bonutti guide sleeve (82) with the Bonutti pusher member (112) to arrive at the claimed invention as claimed in claim 1, nor is it obvious to modify either element to arrive at the claimed invention. In fact Bonutti expressly teaches away from the claimed invention because it discloses that the Bonutti pusher member (112) is free to move relative to the Bonutti guide sleeve (82) along and about the longitudinal axis of the elements. Bonutti teaches that the pusher member (112) is moveable relative to the front annular face to push the anchor down the Bonutti guide sleeve (82) and into a recess in the bone. If the pusher member (112), and the single point projecting from the

distal end of the pusher member, is fixed relative to the front annular face, the pusher member could not push the anchor down the Bonutti guide sleeve (82).

A person having ordinary skill in the art would not be motivated to modify the distal end of the Bonutti guide sleeve (82) to further include a single point projecting distally there from and a shoulder between the face of the distal end of the guide sleeve and the single point. The distal end of the Bonutti guide sleeve (82) has an annular face perpendicular to the longitudinal axis of the Bonutti guide sleeve (82). Bonutti teaches that the distal end of the guide sleeve (82) is inserted to a recess in the bone tissue of substantially the same diameter as the distal end of the guide sleeve (82). (Id.: Col. 5; Ins. 9–13). Bonutti further teaches that an annular face at the distal end of the Bonutti guide sleeve (82) is perpendicular to the longitudinal axis of the Bonutti guide sleeve (82) so that the bone tissue firmly engages the outer side surface of the Bonutti guide sleeve (82) to hold the Bonutti guide sleeve (82) in position relative to the bone recess. (Id.: col. 21–23). The Applicant respectfully submits that there is no motivation to modify the distal end of the Bonutti guide sleeve (82) by including a distal point projecting distally there from because this would seriously reduce the ability of the bone tissue to firmly engage with a sufficient area of the outer side surface of the distal end of the Bonutti guide sleeve (82), resulting in a guide member that is not held in a position relative to the recess as taught by Bonutti.

Finally a person of ordinary skill in the art would not be motivated to include an anchor rotator as required by new independent claim 12. Bonutti teaches a guide sleeve (82) and a coaxial slideable pusher member (112) for pushing and rotating the anchor. However, the examiner has submitted that Bonutti, as shown in the configuration in Fig. 4 anticipates the present invention, wherein the anticipatory guide sleeve comprises the Bonutti guide sleeve (82) in combination with the Bonutti pusher member (112). As stated above, Bonutti is missing an anchor rotator slideably disposed within the hollow longitudinal axis of the Bonutti pusher member (112). A person having ordinary skill in the art would not be motivated to add an anchor rotator slideably disposed

within the Bonutti pusher member (112). First Bonutti teaches that the Bonutti pusher member (112) must have a hollow longitudinal axis to accommodate the suture for attaching the suture anchor with the bone. A person would not be motivated to introduce a pusher member into this channel because it would block the suture. Furthermore, Bonutti already discloses a pusher member (anchor rotator), albeit as a member of the anticipatory guide sleeve as cited to by the Examiner. A person having ordinary skill in the art would not be motivated to use a second anchor rotator, when the device already includes a first anchor rotator (i.e., Bonutti pusher member).

Claims 1–11 Rejected Under 35 U.S.C. § 102(b) by Branch

The Examiner has rejected claims 1–11 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 6,200,322 to Branch et al. (“Branch”). The Applicant respectfully submits that claim 1, as amended, is not anticipated by Branch because Branch does not disclose all of the elements of claim 1.

Branch discloses instrumentation and techniques for spinal body fusion using a minimal exposure posterior surgical approach. (Branch: col. 3, Ins. 9–11). Branch includes a guide sleeve having a proximal end and a distal end. (Branch: col. 7, Ins. 59–69; Figs. 4a and 4b). Branch discloses at least three points (142, 150, 152) projecting distally from the front annular face of the guide sleeve 100, namely an elongated flange (142) and two engagement members (150, 152). (Id.: Fig. 4b). The elongated flange (142) is inserted within a disc space during surgery to provide protection to adjacent vessels and tissue, particularly the great blood vessel and various neurological structures. (Branch: col. 9, Ins. 6–29). One of the engagement members (150 or 152) is anchored in the upper vertebra while the other is anchor in the lower vertebra, thereby securing the guide sleeve (100) in a desired position within the body during use. (Branch: col. 9, Ins. 38–41). Furthermore, Branch discloses a longitudinal opening (134), extending along the entire length of the distal portion (106) and extending across the distal portion from edge to edge. (Branch: Fig. 4b).

Branch does not anticipate the present invention as claimed in claim 1 and claim 12 because Branch is missing the limitation of a single point projecting distally from said front annular face of said guide sleeve as required by independent claims 1 and 12. The Applicant respectfully submits that a single point is equivalent to one point. In contrast Branch discloses at least three points projecting distally from the front annular face of the guide sleeve (100), the elongated flange (142) and the two engagement members (150, 152).

Furthermore, Branch is missing the limitation that the front annular face is substantially planar with the exception of said single point and said shoulder as required by both independent claims 1 and 12. First, as discussed above, Branch discloses a least three points projecting distally from the front annular face of the guide sleeve (100). The Applicant respectfully submits that the front annular face is never planar, i.e. no additional projections, with respect to any one single point because there are always two additional points projecting distally from the front annular face.

Furthermore, Branch is missing the limitation that the front annular face is substantially planar with the exception of the single point and said shoulder because Branch discloses a longitudinal opening (134), extending along the entire length of the distal portion (106) and extending across the distal portion from edge to edge. (Branch: col. 8, Ins. 27–30).

Finally, Branch does not anticipate the present invention as claimed in claim 12 because Branch is missing an anchor rotator slideably disposed within the guide sleeve as required by independent claim 12.

Furthermore, the Applicant respectfully submits that it is not obvious to modify Branch to arrive at the claimed invention as claimed in independent claims 1 and 12. In fact Branch teaches away from the claimed invention because Branch teaches that the distal end of the guide sleeve includes at least two engagement members projecting

distally for anchoring the distal end of the guide sleeve to the vertebra. (Branch: col. 4, Ins. 1–7). Branch further teaches the use of the elongated flange to brace the space between vertebrae during surgery. Branch enables the operator to securely attach the guide sleeve to the vertebra while limiting the freedom of motion by using multiple contact points. The present invention, however, teaches the opposite, namely using only a single projecting point as opposed to a double fork point. (Par. 11–12). By using a single point it is possible for the distal end of the guide sleeve to be applied with great versatility and degree of freedom, but still with a secure fit.

For the foregoing reasons, Applicant respectfully submits that all pending claims, namely Claims 1–21, are patentable over the references of record, and earnestly solicits allowance of the same.

Respectfully submitted,

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